BACTRIM DS- sulfamethoxazole tmp ds tablet
Advanced Rx Pharmacy of Tennessee, LLC

Sulfamethoxazole and Trimethoprim 800mg/160mg tablets #30

Dosage and Administration Section

DOSAGE AND ADMINISTRATION

Sulfamethoxazole and trimethoprim tablets are contraindicated in pediatric patients less than 2 months of age.

Urinary Tract Infections and Shigellosis in Adults and Pediatric Patients, and Acute Otitis Media in Children:

Adults: The usual adult dosage in the treatment of urinary tract infections is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet or 2 sulfamethoxazole and trimethoprim tablets every 12 hours for 10 to 14 days. An identical daily dosage is used for 5 days in the treatment of shigellosis.

Children: The recommended dose for children with urinary tract infections or acute otitis media is 40 mg/kg sulfamethoxazole and 8 mg/kg trimethoprim per 24 hours, given in two divided doses every 12 hours for 10 days. An identical daily dosage is used for 5 days in the treatment of shigellosis. The following table is a guideline for the attainment of this dosage:

Children 2 months of age or older:

Weight
Dose–every 12 hours
lb
kg
Tablets
22
10
–
44
20
1
66
30
1½
88
40
2 or 1 DS tablet

For Patients with Impaired Renal Function: When renal function is impaired, a reduced dosage should be employed using the following table:

Creatinine Clearance (mL/min)
Recommended Dosage Regimen
Above 30
Usual standard regimen
15–30
½ the usual regimen
Below 15
Use not recommended

Acute Exacerbations of Chronic Bronchitis in Adults:

The usual adult dosage in the treatment of acute exacerbations of chronic bronchitis is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet or 2 sulfamethoxazole and trimethoprim tablets every 12 hours for 14 days.

Pneumocystis Jirovecii Pneumonia:

Treatment: Adults and Children:

The recommended dosage for treatment of patients with documented Pneumocystis jirovecii pneumonia is 75 to 100 mg/kg sulfamethoxazole and 15 to 20 mg/kg trimethoprim per 24 hours given in equally divided doses every 6 hours for 14 to 21 days.9 The following table is a guideline for the upper limit of this dosage:

Weight
Dose–every 6 hours
lb
kg
Tablets
18
8
–
35
16
1
53
24
1½
70
32
2 or 1 DS tablet
88
40
2½
106
48
3 or 1½ DS tablets
141
64
4 or 2 DS tablets
176
80
5 or 2½ DS tablets

For the lower limit dose (75 mg/kg sulfamethoxazole and 15 mg/kg trimethoprim per 24 hours) administer 75% of the dose in the above table.

Prophylaxis:

Adults:

The recommended dosage for prophylaxis in adults is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet daily.10

Children:

For children, the recommended dose is 750 mg/m2/day sulfamethoxazole with 150 mg/m2/day trimethoprim given orally in equally divided doses twice a day, on 3 consecutive days per week. The

total daily dose should not exceed 1600 mg sulfamethoxazole and 320 mg trimethoprim.11 The following table is a guideline for the attainment of this dosage in children:

Body Surface Area
Dose– every 12 hours
(m2)
Tablets
0.26
–
0.53
½
1.06
1

Traveler's Diarrhea in Adults:

For the treatment of traveler’s diarrhea, the usual adult dosage is 1 sulfamethoxazole and trimethoprim DS (double strength) tablet or 2 sulfamethoxazole and trimethoprim tablets every 12 hours for 5 days.

Indications and Usage Section

INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of sulfamethoxazole and trimethoprim tablets and other antibacterial drugs, sulfamethoxazole and trimethoprim tablets should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to empiric selection of therapy.

Urinary Tract Infections: For the treatment of urinary tract infections due to susceptible strains of the following organisms: Escherichia coli, Klebsiella species, Enterobacter species, Morganella morganii, Proteus mirabilis and Proteus vulgaris. It is recommended that initial episodes of uncomplicated urinary tract infections be treated with a single effective antibacterial agent rather than the combination.

Acute Otitis Media: For the treatment of acute otitis media in pediatric patients due to susceptible strains of Streptococcus pneumoniae or Haemophilus influenzae when in the judgment of the physician sulfamethoxazole and trimethoprim tablets offers some advantage over the use of other antimicrobial agents. To date, there are limited data on the safety of repeated use of sulfamethoxazole and trimethoprim tablets in pediatric patients under two years of age. Sulfamethoxazole and trimethoprim tablets are not indicated for prophylactic or prolonged administration in otitis media at any age.

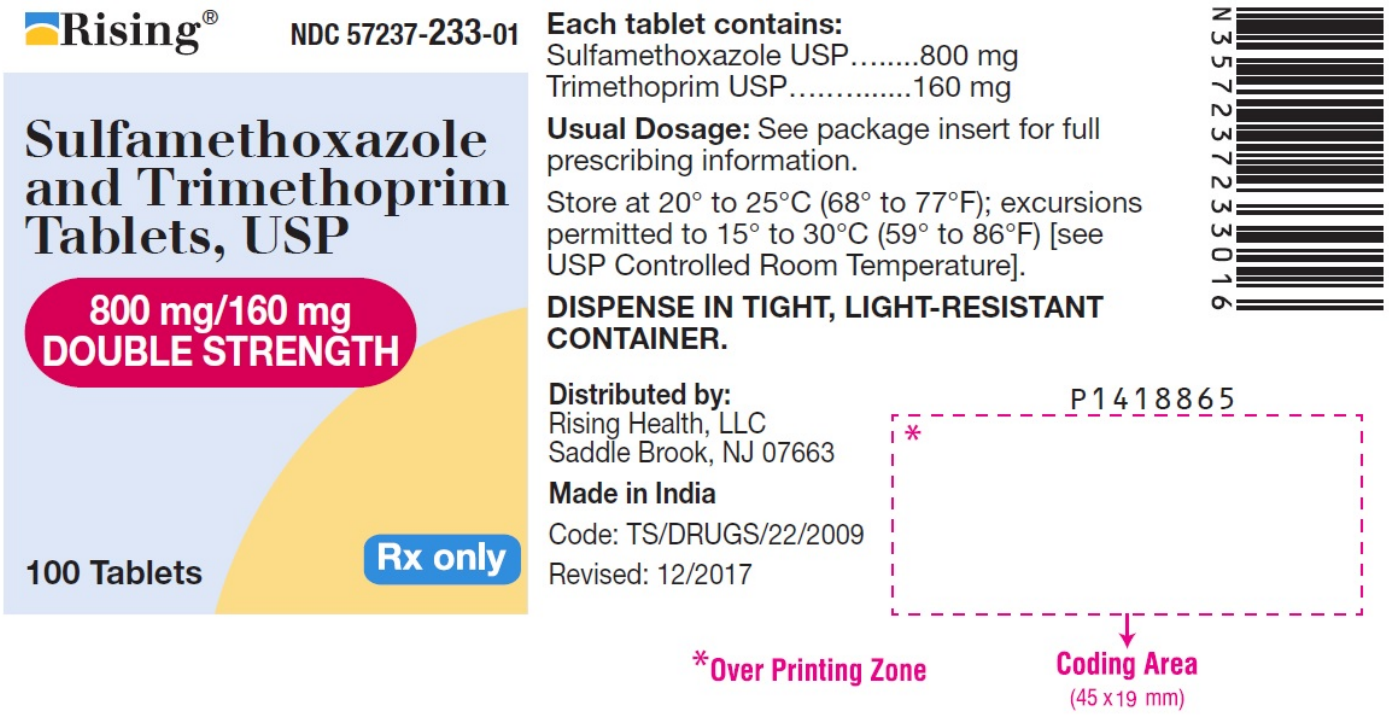
Acute Exacerbations of Chronic Bronchitis in Adults: For the treatment of acute exacerbations of chronic bronchitis due to susceptible strains of Streptococcus pneumoniae or Haemophilus influenzae when a physician deems that sulfamethoxazole and trimethoprim tablets could offer some advantage over the use of a single antimicrobial agent.

Shigellosis: For the treatment of enteritis caused by susceptible strains of Shigella flexneri and Shigella sonnei when antibacterial therapy is indicated.

Pneumocystis jirovecii Pneumonia: For the treatment of documented Pneumocystis jirovecii pneumonia and for prophylaxis against P. jirovecii pneumonia in individuals who are immunosuppressed and considered to be at an increased risk of developing P. jirovecii pneumonia.

Traveler’s Diarrhea in Adults: For the treatment of traveler’s diarrhea due to susceptible strains of enterotoxigenic E. coli.

Principal Display Panel



BACTRIM DS

sulfamethoxazole tmp ds tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0003(NDC:57237-233)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRIMETHOPRIM (UNII: AN164J8Y0X) (TRIMETHOPRIM - UNII:AN164J8Y0X)	TRIMETHOPRIM	160 mg
SULFAMETHOXAZOLE (UNII: JE42381TNV) (SULFAMETHOXAZOLE - UNII:JE42381TNV)	SULFAMETHOXAZOLE	800 mg

Product Characteristics			
Color	white (White)	**Score**	2 pieces
Shape	OVAL (Oval)	**Size**	19mm
Flavor		**Imprint Code**	H;49
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0003-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/16/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090624	02/16/2010	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0003)

Revised: 11/2020 Advanced Rx Pharmacy of Tennessee, LLC